WORK ASSIGNMENT
ENVIRONMENTAL PROTECTION AGENCY

1. CONTRACT NO:	EP-C-10-001	2. CONTRACTOR:	Battelle
3. WORK ASSIGNMENT NO:	0-1	4. AMENDMENT NO:	
5. WA TITLE:	Decontamination of Materials Contaminated with *Bacillus Anthracis* spores with Ozone		

6. CHECK APPLICABLE BOXES:

[ ] ORIGINAL WA | [ ] WA AMENDMENT | [X] WP APPROVAL | [ ] OTHER:

7. PERIOD OF PERFORMANCE * DATE OF CO APPROVAL UNLESS OTHERWISE SPECIFIED ** INCLUDES ALL DELIVERABLES	*FROM 3/29/10	CO Approval	**TO 8/31/10	

8. LEVEL OF EFFORT ORDERED:	441 hours

9. ACCOUNTING AND APPROPRIATION DATA

APPROPRIATION NO.	DOCUMENT CONTROL NO.	ACCOUNT NO.	AMOUNT *
	4B0095		
* TOTAL WA FUNDING CEILING			

WORK PLAN APPROVAL

10. CONTRACTOR WP DATED	April 14, 2010	TOTAL COSTS:	$64,751	TOTAL LOE:	~~440 hours~~ 425
11. CUMULATIVE APPROVED TO DATE:		TOTAL COSTS:		TOTAL LOE:	

12. DOES WP REQUIRE SUBCONTRACTOR OR CONSULTANT?	[ ] YES	[X] NO
IF YES, HAS SUBCONTRACTOR/CONSULTANT BEEN INCORPORATED INTO THE CONTRACT?	[ ] YES	[ ] NO

13. APPROVALS

WORK ASSIGNMENT MANAGER NAME:	Joseph P. Wood	BRANCH/MAIL CODE:	NHSRC/E343-06
	4/21/10	PHONE NO:	919-541-5029
(SIGNATURE)	(DATE)	FAX NO:	919-541-0496
PROJECT OFFICER NAME:	Shannon D. [illegible]	BRANCH/MAIL CODE:	NHSRC/E343-06
Shannon Serre	April 21, 2010	PHONE NO:	919-541-3817
(SIGNATURE)	(DATE)	FAX NO:	919-541-0496
OTHER APPROVING OFFICIAL NAME:		BRANCH/MAIL CODE:	
		PHONE NO:	
(SIGNATURE)	(DATE)	FAX NO:	
CONTRACTING OFFICER NAME:	Lynne W. Lewis	BRANCH/MAIL CODE:	CPOD-NWD
** Lynne W. Lewis	04/26/10	PHONE NO:	513-487-2040
(SIGNATURE)	(DATE)	FAX NO:	513-487-2109

** Effective Date of WP Approval or WA Issuance (per contract)

CONTRACTOR'S REPRESENTATIVE ACKNOWLEDGEMENT

SIGNATURE:	TITLE:	DATE:

STATEMENT OF WORK
Contract EP-C-10-001
Work Assignment 0-1

I. TITLE
Decontamination of Materials with Ozone Gas

II. PERIOD OF PERFORMANCE
The period of performance for the tasks detailed in this Statement of Work (SOW) shall be until August 31, 2010.

III. SUMMARY OF OBJECTIVES
This work will provide data on the effectiveness of ozone gas to inactivate *B. anthracis* spores on different materials.

IV. RELEVANCE
The results of these tests will provide the decontamination technology user and stakeholder with high quality, peer-reviewed data on the effectiveness of ozone gas to decontaminate building materials contaminated with *B. anthracis* and a surrogate. The results of the work will be made available to the homeland security and emergency response community through published reports, journal papers, and/or conference presentations/proceedings. The information will also be used to develop guidance documents pertaining to specific threat agents and release scenarios.

V. BACKGROUND
The U.S. Environmental Protection Agency (EPA) has the responsibility for protecting human health and the environment from accidental and intentional releases of hazardous and toxic materials. According to Homeland Security Presidential Directive 10 (HSPD-10), the EPA is tasked with developing strategies, guidelines, and plans for decontamination of persons, equipment, and facilities following a biological weapons attack. In response to this directive, the EPA Office of Research and Development (ORD) National Homeland Security Research Center's (NHSRC) Decontamination and Consequence Management Division (DCMD) is investigating methods and technologies for the inactivation of spores (e.g., *Bacillus anthracis* Ames) on materials/surfaces. This work will build on the decontamination studies that have already been conducted.

VI. SCOPE

The purpose of the study is to investigate the use of ozone gas to decontaminate different types of materials inoculated with *B. anthracis* spores. Sufficient replicates, blanks, and positive controls shall be used, consistent with standard microbiological and quality assurance procedures, past work conducted by the contractor, and studies being currently conducted by the contractor.

VII. TECHNICAL APPROACH

For each decontamination test, the effort shall include the recovery of viable agent from each material before (positive control) and after decontamination. Five replicates for each agent-material combination shall be included in each experiment. All experiments described below shall be approved by the EPA Work Assignment Manager (WAM) prior to commencement. Test and analytical methods shall be adopted from past or on-going efforts, in consultation with the WAM.

VIII. TASKS 1-2

The Contractor shall perform the following tasks:

1. Prepare an amendment to an existing quality assurance/test plan (QATP), which will be provided by the WAM and which pertains to ozone gas decontamination test procedures. The amendment shall cover the experiments as described in Task 2 of this SOW.

2. Conduct experiments to quantitatively determine the effectiveness (log reduction) of inactivating *B. anthracis* (Ames strain) spores and one surrogate specie (to be determined by the WAM during the writing of the QATP amendment, but will most likely be either *B. subtilis* or *Geobacillus stearothermophilus*) on different material coupons using ozone gas. Six material types shall be used for testing, and shall include glass, wood, carpet, laminate, metal ductwork and painted wallboard paper. (The same materials used in previous projects with the contractor). The experimental matrix shall include tests to be conducted at two different ozone concentrations, three contact times, and two different relative humidity (RH) levels (e.g., 70 and 85 %). The first test condition will be provided by the WAM at the time of developing the QATP amendment. The remaining test conditions will be determined based on the results of the first experiment and provided by the WAM. Tests shall be conducted in a small chamber, consistent with previous tests of fumigants conducted under previous projects with this contractor. Tests shall include a sufficient number of replicates, positive controls, and blanks - consistent with previous projects. Finally, a qualitative assessment of the impacts this technology has on the coupon materials (such as structural damage, surface degradation, discoloration, odor, and other aesthetical impacts) shall be noted for each test.

IX. QUALITY ASSURANCE

The awardee shall comply with all requirements as delineated on the "Quality Assurance Planning Requirements Form (QARF)" included with this extramural action; see attachment #1 and #2. The contractor shall prepare a QAPP in accordance with http://www.epa.gov/quality/qs-docs/r5-final.pdf or based on the type of research that is being conducted. For guidance on preparing a research-specific QAPP, the preparer should refer to the project specific requirements provided in NHSRC's QMP. The QAPP shall be approved prior to the start of any laboratory work. Additional information related to QA requirements can be found at www.epa.gov/quality.

X. DELIVERABLE SCHEDULE

1. Transfer of project data shall occur via electronic mail at the conclusion of each test. These data shall include, but not be limited to, ozone level, temperature, RH, and viable organism counts for test and control coupons.

Task	Begin date	Completion Date
1. QATP amendment	Right away	1 month after WA awarded
2. Task 2 testing	completion of QAPP	August 31, 2010

WORK ASSIGNMENT
ENVIRONMENTAL PROTECTION AGENCY

1. CONTRACT NO:	EP-C-10-001	2. CONTRACTOR:	Battelle
3. WORK ASSIGNMENT NO:	0-2	4. AMENDMENT NO:	
5. WA TITLE:	Decontamination of Materials with Liquid and Gaseous Chlorine Dioxide		

6. CHECK APPLICABLE BOXES:

[ ] ORIGINAL WA | [ ] WA AMENDMENT | [X] WP APPROVAL | [ ] OTHER:

7. PERIOD OF PERFORMANCE * DATE OF CO APPROVAL UNLESS OTHERWISE SPECIFIED ** INCLUDES ALL DELIVERABLES	*FROM 3/29/10	CO Approval	**TO 8/31/10	

8. LEVEL OF EFFORT ORDERED:	871 hours

9. **ACCOUNTING AND APPROPRIATION DATA**

APPROPRIATION NO.	DOCUMENT CONTROL NO.	ACCOUNT NO.	AMOUNT *
	4B0094		
* TOTAL WA FUNDING CEILING			

WORK PLAN APPROVAL

10. CONTRACTOR WP DATED	April 14, 2010	TOTAL COSTS:	$142,698	TOTAL LOE:	[redacted] hours 840
11. CUMULATIVE APPROVED TO DATE:		TOTAL COSTS:		TOTAL LOE:	

12. DOES WP REQUIRE SUBCONTRACTOR OR CONSULTANT? [ ] YES [X] NO
IF YES, HAS SUBCONTRACTOR/CONSULTANT BEEN INCORPORATED INTO THE CONTRACT? [ ] YES [ ] NO

13. **APPROVALS**

WORK ASSIGNMENT MANAGER NAME:	Joseph P. Wood	BRANCH/MAIL CODE:	NHSRC/E343-06
	4/21/10	PHONE NO:	919-541-5029
(SIGNATURE)	(DATE)	FAX NO:	919-541-0496
PROJECT OFFICER NAME:	Shannon D. Serre	BRANCH/MAIL CODE:	NHSRC/E343-06
Shannon Serre	April 21, 2010	PHONE NO:	919-541-3817
(SIGNATURE)	(DATE)	FAX NO:	919-541-0496
OTHER APPROVING OFFICIAL NAME:		BRANCH/MAIL CODE:	
		PHONE NO:	
(SIGNATURE)	(DATE)	FAX NO:	
CONTRACTING OFFICER NAME:	Lynne W. Lewis	BRANCH/MAIL CODE:	CPOD-NWD
** Lynne W. Lewis	04/26/10	PHONE NO:	513-487-2040
(SIGNATURE)	(DATE)	FAX NO:	513-487-2109

** Effective Date of WP Approval or WA Issuance (per contract)

CONTRACTOR'S REPRESENTATIVE ACKNOWLEDGEMENT

SIGNATURE:	TITLE:		DATE:

STATEMENT OF WORK
Contract EP-C-10-001
Work Assignment 0-2

I. TITLE
Decontamination of Materials with Liquid and Gaseous Chlorine Dioxide

II. PERIOD OF PERFORMANCE
The period of performance for the tasks detailed in this Statement of Work (SOW) shall be until August 31, 2010.

III. SUMMARY OF OBJECTIVES
This work will provide data on the effectiveness of chlorine dioxide (ClO_2) gas to inactivate *B. anthracis* spores in soil. This work will also provide data on the effectiveness of aqueous solutions of ClO_2 to inactivate *B. anthracis* spores on different materials.

IV. RELEVANCE
The results of these tests will provide the decontamination technology user and stakeholder with high quality, peer-reviewed data on the effectiveness of liquid and gaseous ClO_2 to decontaminate soil and other materials contaminated with *B. anthracis* and a surrogate. The results of the work will be made available to the homeland security and emergency response community through published reports, journal papers, and/or conference presentations/proceedings. The information will also be used to develop guidance documents pertaining to specific threat agents and release scenarios.

V. BACKGROUND
The U.S. Environmental Protection Agency (EPA) has the responsibility for protecting human health and the environment from accidental and intentional releases of hazardous and toxic materials. According to Homeland Security Presidential Directive 10 (HSPD-10), the EPA is tasked with developing strategies, guidelines, and plans for decontamination of persons, equipment, and facilities following a biological weapons attack. In response to this directive, the EPA Office of Research and Development (ORD) National Homeland Security Research Center's (NHSRC) Decontamination and Consequence Management Division (DCMD) is investigating methods and technologies for the inactivation of spores (e.g., *Bacillus anthracis* Ames) on materials/surfaces. This work will build on the decontamination studies that have already been conducted.

VI. SCOPE

The purpose of the study is to investigate the use of ClO_2 gas to decontaminate soil. It is expected that the Sabre ClO_2 generator will be used for this project. Aqueous solutions of ClO_2, prepared using the Sabre system as well, will also be tested for decontamination efficacy on different types of materials inoculated with *B. anthracis* spores. Sufficient replicates, blanks, and positive controls shall be used, consistent with standard microbiological and quality assurance procedures, past work conducted by the contractor,

and studies being currently conducted by the contractor.

VII. TECHNICAL APPROACH

For each decontamination test, the effort shall include the recovery of viable agent from each material before (positive control) and after decontamination. Five replicates for each agent-material combination shall be included in each experiment. All experiments described below shall be approved by the EPA Work Assignment Manager (WAM) prior to commencement. Test and analytical methods shall be adopted from past or on-going efforts, in consultation with the WAM.

VIII. TASKS

The Contractor shall perform the following tasks:

1. Prepare a quality assurance/test plan (QATP) for the experiments in Tasks 2 and 3 related to decontamination of soil using ClO_2 gas. Microbiological procedures, soil coupons and measurement of temperature, relative humidity (RH), and ClO_2 levels shall be consistent with procedures used under previous projects with EPA.

2. Conduct experiments to quantitatively determine the effectiveness (log reduction) of inactivating *B. anthracis* (Ames strain) and *B. subtilis* spores in two different soil types using ClO_2 gas generated with the Sabre system. The soil types to use for testing will be determined by the WAM during the writing of the QATP, but will most likely include a topsoil from a retail provider, and a standard soil such as Arizona Road Dust. For each microorganism and soil, six tests shall be conducted: tests at two ClO_2 concentrations and three contact times. Temperature, RH, and ClO_2 concentration shall be measured and controlled during fumigation tests.

3. Conduct triplicate tests using standard methods to determine the moisture and organic content of the two test soils described in Task 2.

4. Prepare an amendment to an existing quality assurance/test plan (QATP), which will be provided by the WAM and which pertains to decontamination tests using liquid spray sporicides. The amendment shall cover the experiments as described in Tasks 5 -7 of this SOW. Microbiological procedures, coupons and measurement of ClO_2 levels shall be consistent with procedures used in previous projects with the WAM.

5. Conduct experiments to quantitatively determine the effectiveness (log reduction) of inactivating *B. anthracis* (Ames strain) and *B. subtilis* spores on coupon materials by spraying (e.g., using a small hand held spray bottle) aqueous ClO_2 solutions generated with the Sabre system. Up to eight tests shall be conducted initially on galvanized metal coupons using various ClO_2 concentrations, application rates, and contact times in order to optimize decontamination efficacy.

6. Once a ClO_2 concentration, application rate, and contact time combination has

been determined to be the most effective under Task 5, one test shall be conducted at that condition on five additional materials. These additional materials will be determined by the WAM at the time of writing the QATP amendment under task 4, but are expected to be materials such as topsoil, glass, wood, carpet, laminate, and wallboard paper.

7. For the tests conducted in Tasks 5 and 6, the ClO_2 level and pH of the test solutions shall be measured.

8. Tests shall include a sufficient number of replicates, positive controls, and blanks - consistent with previous projects. Finally, a qualitative assessment of the impacts this technology has on the coupon materials (such as structural damage, surface degradation, discoloration, odor, and other aesthetical impacts) shall be noted for each test.

IX. QUALITY ASSURANCE

The awardee shall comply with all requirements as delineated on the "Quality Assurance Planning Requirements Form (QARF)" included with this extramural action; see attachment #1 and #2. The contractor shall prepare a QAPP in accordance with http://www.epa.gov/quality/qs-docs/r5-final.pdf or based on the type of research that is being conducted. For guidance on preparing a research-specific QAPP, the preparer should refer to the project specific requirements provided in NHSRC's QMP. The QAPP shall be approved prior to the start of any laboratory work. Additional information related to QA requirements can be found at www.epa.gov/quality.

X. DELIVERABLE SCHEDULE

1. Transfer of project data shall occur via electronic mail at the conclusion of each test. These data shall include, where appropriate, ClO_2 level, temperature, RH, pH, and viable organism counts for test and control coupons.

Task	Begin date	Completion Date
Task 1 QATP	Right away	1 month after WA awarded
Task 2 testing	completion of QATP	August 31, 2010
Task 3	Completion of QATP	August 31, 2010
Task 4	Right away	1 month after WA awarded
Task 5	Completion of Task 4	3 months after start of experiments
Task 6	After completion of task 5	August 31, 2010

WORK ASSIGNMENT
ENVIRONMENTAL PROTECTION AGENCY

1. CONTRACT NO:	EP-C-10-001	2. CONTRACTOR:	Battelle
3. WORK ASSIGNMENT NO:	0-3	4. AMENDMENT NO:	
5. WA TITLE:	*ENZYMATIC DECONTAMINATION OF CHEMICAL WARFARE AGENTS*		

6. CHECK APPLICABLE BOXES:

[ ] ORIGINAL WA | [ ] WA AMENDMENT | [X] WP APPROVAL | [ ] OTHER:

7. PERIOD OF PERFORMANCE * DATE OF CO APPROVAL UNLESS OTHERWISE SPECIFIED ** INCLUDES ALL DELIVERABLES	*FROM	CO Approval	**TO 8/31/10	

8. LEVEL OF EFFORT ORDERED:	670 hours

9. **ACCOUNTING AND APPROPRIATION DATA**

APPROPRIATION NO.	DOCUMENT CONTROL NO.	ACCOUNT NO.	AMOUNT *
* TOTAL WA FUNDING CEILING			

WORK PLAN APPROVAL

10. CONTRACTOR WP DATED	May 21, 2010	TOTAL COSTS:	$94,864	TOTAL LOE:	670 hours
11. CUMULATIVE APPROVED TO DATE:		TOTAL COSTS:		TOTAL LOE:	

12. DOES WP REQUIRE SUBCONTRACTOR OR CONSULTANT?	[ ] YES	[X] NO
IF YES, HAS SUBCONTRACTOR/CONSULTANT BEEN INCORPORATED INTO THE CONTRACT?	[ ] YES	[ ] NO

13. **APPROVALS**

WORK ASSIGNMENT MANAGER NAME:	Lukas Oudejans		BRANCH/MAIL CODE:	NHSRC/E343-06
Oudejans	5/24/2010		PHONE NO:	919-541-2973
(SIGNATURE)	(DATE)		FAX NO:	919-541-0496
PROJECT OFFICER NAME:	Shannon D. Serre		BRANCH/MAIL CODE:	NHSRC/E343-06
Shannon Serre	5/24/2010		PHONE NO:	919-541-3817
(SIGNATURE)	(DATE)		FAX NO:	919-541-0496
OTHER APPROVING OFFICIAL NAME:			BRANCH/MAIL CODE:	
			PHONE NO:	
(SIGNATURE)	(DATE)		FAX NO:	
CONTRACTING OFFICER NAME:	Lynne W. Lewis		BRANCH/MAIL CODE:	CPOD-NWD
** Lynne Lewis	05/27/10		PHONE NO:	513-487-2040
(SIGNATURE)	(DATE)		FAX NO:	513-487-2109

** Effective Date of WP Approval or WA Issuance (per contract)

CONTRACTOR'S REPRESENTATIVE ACKNOWLEDGEMENT

SIGNATURE:		TITLE:		DATE:	

STATEMENT OF WORK
Contract EP-C-10-001

ENZYMATIC DECONTAMINATION OF CHEMICAL WARFARE AGENTS

OMIS DCMD 3.48

TABLE OF CONTENTS

I. TITLE

Enzymatic Decontamination of Chemical Warfare Agents

II. PERIOD OF PERFORMANCE

The period of performance for the tasks detailed in this Statement of Work (SOW) shall be until August 31, 2010.

III. SUMMARY OF OBJECTIVES

This work will provide efficacies of enzymatic decontamination methods for chemical agent decontamination. Currently NHSRC is systematically evaluating decontamination methods such as chlorine dioxide (ClO_2) fumigant and hydrogen peroxide (H_2O_2) fumigant for the decontamination of various chemical warfare agents (CWA) on building material coupons. The detrimental effect (e.g., corrosion) that these fumigants have on various surfaces types is well documented. Enzymatic decontamination on the other hand is considered to be far more benign. This work will determine the efficacy of this decontamination method as a function of the building material. This work assignment will cover the evaluation of the DEFENZ VX-G enzyme product as commercially available by Genencor for the decontamination of chemical agents thickened soman (TGD) and VX on multiple interior building materials.

IV. RELEVANCE

The eminent threat of a chemical agent release in a building or transportation hub is driving US EPA's National Homeland Security Research Center (NHSRC) Decontamination and Consequence Management Division (DCMD) to develop a research program that systematically evaluates potential decontaminants of chemical agents. US EPA is tasked to cleanup these agents after they are released which is complicated by the fact that it is unknown how effective many of the available decontamination technologies are against chemical agents. In addition, the optimal decontaminant concentration and contact time have primarily been determined by the vendors. It is known that some of these decontaminants produce, possible toxic, by-products when they react with the chemical agents. In this work, the efficacy of an enzymatic decontamination solution will be systematically evaluated against two agents and the by-products from these decontaminations will be assessed. The effect of the enzymatic decontaminants on the building materials will also be assessed qualitatively.

V. BACKGROUND

Protecting human health and the environment from the release of hazardous materials is the mission of US EPA. NHSRC-DCMD has developed a systematic decontamination research program to fulfill this mission. As a part of this program, developmental and commercially available decontamination technologies for chemical agents are being systematically evaluated.

Enzymes would appear to be the ideal decontamination method – safe and environmentally benign. They may generally become more appropriate alternatives for existing decontamination technologies against chemical (and possibly biological) agents. Enzymes are less hazardous, less corrosive, and environmentally compatible and would lower the logistical and operational burden related to decontamination. They require low quantities for use (typically 10-100g of enzymes for every 1 kg of CWA to be decontaminated) and are, therefore, easy to store and ship. The Department of Defense (DoD) has completed a substantial amount of research on the development of enzymes for CWA decontamination. Proof of concepts included large scale decontamination of military vehicles using a foam application of enzymes. DoD research has not been extended into decontamination of indoor building materials.

Many biological sources have been identified for the organophosphorus acid anhydrolase (OPAA) and the organophosphorus hydrolase (OPH) enzymes that could denature selected CWAs, namely G-agents and VX, respectively. Enzymatic decontamination of sulfur mustard (HD) has been reported for chloroperoxidase (CPO) and dehalogenase (DHG) enzymes but those are not commercially available for large scale decontamination purposes and are therefore not under consideration at this time. Disadvantages of enzymes in general can be found in their inability to work in harsh (elevated temperatures and/or high/low pH) environments, however, improvements in stability have made enzymes now suitable for decontamination in ambient indoor and outdoor like conditions. Enzyme inhibition due to a presence of e.g. proteins on the surface of the building material may play a role in the overall decontamination efficiency. However, at this time only ideal, clean surfaces contaminated with a CWA will be used to determine the efficacies of this enzyme solution.

VI. SCOPE

The overall objective of this work is to systematically evaluate a commercially available enzyme solution as a decontaminant for chemical agents thickened soman (TGD) and VX. As part of this project, the efficacy of this decontaminant shall be determined as function of building material for one contact time with the solution. In addition, the effects of the decontaminant on five building materials shall be determined by visual inspection along with the by-products from the decontamination of the chemical agent.

VII. TECHNICAL APPROACH

Details for the general technical approach can be found in Section VIII but the overall technical approach follows the same approach as established under the Technology Testing and Evaluation Program (TTEP) Task Order (TO) 1140 under contract GS-23F0011L. In that TO, a test method was developed to test liquid decontaminants similar to how they would be used in the field for chemical agents. Most of the method development under TO 1140 shall be applied here as well. Prior to the actual decontamination test, the contractor shall only develop one extraction method of the CWA for one building material that was not part of TO 1140. During the decontamination testing with enzymes, the decontamination efficacy shall be determined and decontamination by-

products shall be identified. Materials effects shall also be visually assessed. The test/QA plan for each experiment within each task shall be approved by the EPA WAM prior to commencement, once the data have been transferred and discussed as outlined in Section IX.

VIII. TASKS

The contractor shall perform the following tasks:

TASK 1. PREPARATION OF TEST/QA PLAN

The awardee shall comply with all requirements as delineated on the "Quality Assurance Planning Requirements Form (QARF)" included with this extramural action, see attachment #1 and #2. The contractor shall prepare a QAPP in accordance with http://www.epa.gov/quality/qs-docs/r5-final.pdf and the NHSRC Quality Assurance (QA) requirement as defined in Attachment #2 to the SOW. For guidance on preparing a research-specific QAPP, the preparer should refer to the project specific requirements provided in NHSRC's Quality Management Plan (QMP). The draft QAPP will be reviewed by the EPA WAM and the EPA Quality Assurance Manager. The contractor shall respond to comments and submit the QAPP approval to the EPA WAM and EPA Quality Assurance Manager. The QAPP, including any amendments, shall be approved by the U.S. EPA in writing (e.g., signature on the approval page) prior to the start of any work. Additional information related to QA requirements can be found at: http://www.epa.gov/quality/qs-docs/r5-final.pdf.

This QAPP shall be generic in that it will cover any enzyme based decontamination solution chosen by the EPA WAM. It shall include a comprehensive work plan and a timetable for completion of the work. The QAPP shall be amended as needed to include any modifications to the test plan. In this test plan the test matrices shall include laboratory blanks, positive controls, solution controls, and procedural blanks in addition to the test coupons. Solution controls are defined as controls where the target coupon with the CWA applied to its surface is able to interact with the enzyme-free solution. Such solution control will determine the true effect of enzymes on the decontamination of the surface. The specific solution for the enzyme will be provided by the manufacturer of the enzyme product.

TASK 2. PROCUREMENT OF THE ENZYME PRODUCT

The contractor shall start procurement of the enzyme products DEFENZ VX-G from the manufacturer Genencor within 30 days of award of the work assignment.

TASK 3. METHOD DEVELOPMENT - EXTRACTION OF CHEMICAL AGENTS FROM VINYL FLOORING MATERIAL COUPON

An important variable in technology verification is the underlying surface type. For that reason, the contractor shall perform tests on the following five building material coupons: two flooring materials (wood and vinyl), galvanized metal ductwork, decorative laminate,

and industrial grade carpet. The size of the building material coupons shall be 4.0 by 2.5 cm. Brand characteristics will be provided by the EPA WAM. The contractor shall procure and prepare the coupons.

The contractor shall prepare the enzyme solution by following the instructions as provided by the manufacturer, Genencor. A fresh solution shall be prepared at the beginning of each day of the systematic evaluation as described in Task 4. The contractor shall record the time difference between the time of preparation and time of usage of the enzyme solution for quality control purposes. The contractor shall also measure the pH of the enzyme solution prior to application on a daily basis.

The EPA WAM will provide the contractor with the thickening method for the GD during the drafting of the QAPP. Extraction methods of the CWA from the building materials have been developed under TO 1140 for four of the five building material and the contractor shall use these extraction methods. For the fifth building material, vinyl flooring, the contractor shall develop an extraction method for extracting TGD and VX. This extraction method, including solvent selection, shall be designed upon consultation with the EPA WAM. This study shall include three replicates for each agent for the vinyl flooring material. The extraction efficiencies shall fall in the range of 40% to 120% with less than a 30% coefficient of variance between the three samples. The EPA WAM may approve extraction efficiencies and coefficients of variances that are not in this range. Therefore, if an extraction procedure does not meet this criterion, the contractor shall consult with the EPA WAM to determine the next step. Additional extraction methods development beyond what is stated above may result in reduction of the scope in Task 4 "Systematic Evaluation of Enzymatic Decontamination Solutions". Prior to continuing to Task 4, the contractor shall report the extraction efficiencies for the two agents / vinyl flooring material to the EPA WAM. Work on Task 4 in this SOW shall not begin until the EPA WAM provides a written approval (electronic mail is sufficient) of the extraction efficiencies.

A method detection limit study for TGD and VX on four of the five building materials was performed under TO 1140 and shall not be repeated. Only a method detection limit study for TGD and VX shall be completed for vinyl flooring. The method detection limit study shall follow the single concentration design estimator recommended by the EPA (40 CFR part 136, Appendix B (1984) Definition and Procedure for Determination of the Method Detection Limit).

Repeating extraction methods or method detection limit studies beyond what has been established under TO 1140 or explicitly described in this task is considered out of the scope of this statement of work.

TASK 4. SYSTEMATIC EVALUATION OF ENZYMATIC DECONTAMINATION SOLUTIONS

Application of the enzyme solution in the field would occur as a spray. Therefore, the contractor shall first determine the amount of enzyme solution applied to a 4.0 by 2.5 cm coupon size during spraying following the developed method under TO 1140. The

contractor shall also develop a method to quench (neutralize) the enzyme decontamination reaction such that three different exposure times can be evaluated.

A test matrix shall be constructed using five building materials and two agents for one exposure time and the decontamination efficiency shall be obtained for each test. At least 5 replicates of test coupons, 5 replicates of positive controls, 5 replicates of solution controls, and 2 replicates of procedural blanks shall be analyzed for each agent/enzyme/material combination for one exposure time. Solution controls are defined as controls where CWA-contaminated coupon interacts with the enzyme solution without the enzyme present in the solution. Information regarding the specific solution for the enzyme (most likely buffered water) will be provided by the manufacturer of the enzyme product. The applied solution for this control type shall be amended to match the recorded pH of the enzyme solution.

The full matrix for is shown in Table 1. Absolute exposure time will be provided by the WAM at the time of developing the QAPP but will be in the range of 10 to 20 minutes.

Table 1: Test matrix for systematic decontamination with enzymes

		Sample Type				
Agent	Material	Test Coupons	Positive Controls	Solution Controls	Procedural Blanks	Laboratory Blanks
VX	Galvanized Metal	5*	5*	5*	2*	2*
VX	Decorative Laminate	5	5	5	2	2
VX	Industrial Carpet	5*	5*	5*	2*	2*
VX	Wood Flooring	5	5	5	2	2
VX	Vinyl Flooring	5	5	5	2	2
TGD	Galvanized Metal	5*	5*	5*	2*	2*
TGD	Decorative Laminate	5	5	5	2	2
TGD	Industrial Carpet	5*	5*	5*	2*	2*
TGD	Wood Flooring	5	5	5	2	2
TGD	Vinyl Flooring	5	5	5	2	2

The contractor shall have 95 samples for analysis per agent giving a total of 190 samples for the complete decontamination test matrix. The CWA amount present on a coupon shall be determined by GC-FPD or GCMS analysis of the extraction solvent as developed under previous task orders, including TO 1140.

The contractor shall perform a qualitative assessment of decontamination by-products for samples marked (*) in Table 1.0 using full scan GCMS.

Last of all, the effect of the enzyme decontamination solution on the materials shall be determined. The integrity of the materials shall be tested using visual inspection and documented with (digital) photographs taken before the decontamination solution is applied and at the end of the interaction time of the enzyme solution with the CWA.

TASK 5. QUALITATIVE ASSESSMENT OF VX DECONTAMINATION BY-PRODUCTS

The contractor shall perform a qualitative assessment of the decontamination by-products formed from the reaction of VX with the liquid enzyme decontamination solution DEFENZ VX-G without the presence of a building material substrate and for the same interaction time as used in the previous task. A general extraction procedure using a polar solvent for subsequent analysis via liquid chromatography mass spectrometry (LC-MS) shall first be developed by the contractor upon consultation with the EPA WAM. The contractor shall then use this extraction and analysis procedure for analysis of solutions of VX that have been decontaminated with the enzyme solution and afterward neutralized. In addition, blank neutralized enzyme decontamination solutions shall also be extracted and analyzed using the same extraction and LC-MS procedure. The test matrix for this task is shown in Table.

Table 2: Full test matrix for LC-MS by-product analysis

Agent	Sample Type	# replicates
VX	DEFENZ VX-G Enzyme solution with Chemical Agent	3
None	Neutralized enzyme solution	3

IX. DELIVERABLE SCHEDULE

1. Bi-weekly conference calls shall be established between the EPA WAM and the contractor project officer. During these conference calls the contractor shall report on progress made in the project and any technical issues encountered in implementation of the test plan.

2. A QAPP that covers research efforts described under Task 3 to 5 shall be submitted to the EPA WAM within 30 days of award of the work assignment. The EPA WAM will then coordinate peer and EPA QA review of the QAPP. The contractor shall then address any comments resulting from these reviews within 15 days of receipt of the comments. The contractor shall then provide a final copy of the QAPP both in electronic and hard copy for EPA approval. Work covered in this contract shall not begin until the QAPP has been approved by the EPA Quality Assurance Manager. The QAPP shall contain work plans detailing how the experiments will be run and include a timetable for task completion. The awardee shall adhere to QA requirements as delineated in "Attachment #1 and 2" to this SOW.

3. Transfer of project data (including raw data) shall occur via electronic mail at the conclusion of each experiment within each task.

4. A detailed written summary of experimental procedures shall be provided to the WAM at the conclusion of this WA. This report shall indicate the exact operational conditions (e.g. enzyme solution preparation procedure and exposure time), raw peak areas from the mass spectra, the calibration data sets for the GC-MS of the coupon extracts, the measured agent concentrations on all of the coupons (test coupons, procedural blanks, positive controls, solution controls, and laboratory blanks). In relation to Task 5, the report shall indicate the operational conditions of the LC-MS and the raw mass spectra data for detected by-products that are identified as by-products of the decontamination process for all samples.

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 0-04

☐ Other ☐ Amendment Number:

Contract Number: EP-C-10-001

Contract Period: Base | Option Period Number 2

Title of Work Assignment/SF Site Name: Evaluation of Pressurized Water Clean

Contractor: Battelle

Specify Section and Paragraph of Contract SOW: Section 3.1

Purpose:
☐ Work Assignment
☐ Work Assignment Amendment
☒ Work Plan Approval
☐ Work Assignment Close-Out
☐ Incremental Funding

Period of Performance: From 7/23/10 To 8/31/10

Comments: Evaluation of Pressurized Water Cleaning System for Removal of Improvised Nuclear Device Contamination from Urban Surfaces

☐ Superfund — Accounting and Appropriations Data — ☐ Non-Superfund

Note: To report additional accounting and appropriations data use EPA Form 1900-69A.

SFO (Max 2): 22

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period:	$19,847	102 LOE
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: EMILY SNYDER
(Signature) 08/10/10 (Date)
Branch/Mail Code: DCMD/E343-06
Phone Number: 919-541-1006
FAX Number: 919-541-0496

Project Officer Name: SHANNON SERRE
(Signature) 8/10/10 (Date)
Branch/Mail Code: DCMD/E343-06
Phone Number: 919-541-3817
FAX Number: 919-541-0496

Other Agency Official Nan
(Signature) (Date)
Branch/Mail Code:
Phone Number:
FAX Number:

Contracting Officer Name: LYNNE LEWIS
(Signature) 08/20/10 (Date)
Branch/Mail Code: CPOD/NWD
Phone Number: 513-487-2040
FAX Number: 513-487-2109

Work Assignment Form. (WebForms v1.0)

STATEMENT OF WORK

EVALUATION OF PRESSURIZED WATER CLEANING SYSTEM FOR REMOVAL OF IND CONTAMINATION FROM URBAN SURFACES

OMIS DCMD 3.35A

TABLE OF CONTENTS

I. PERIOD OF PERFORMANCE

The period of performance for the tasks detailed in this Statement of Work (SOW) shall end 12 months from the award date of the contract.

II. SUMMARY OF OBJECTIVES

The performance of a pressurized water system, specifically a rotating jet with a shroud, shall be evaluated for the removal of simulated Improvised Nuclear Device (IND) fallout particles from coarse concrete. This work is based on similar evaluations accomplished under the EPA's Technology Testing and Evaluation Program (TTEP), which has developed the test methods, protocols, Quality Assurance Project Plans (QAPP), and facilities applicable to this Statement of Work. It is anticipated that these previously developed products will be used or adapted to the greatest extent possible. Modifications in contamination methods and detection will be necessary because the contaminant is different (simulated fallout) than what was previously tested (CsCl). An additional requirement of this Work Assignment (WA) shall be for the contractor to develop simulated fallout upon consultation with the EPA Work Area Manager (WAM).

The technology performance evaluations shall include the determination of the amount of any remaining contamination following application of the decontamination technologies, and shall evaluate specific parameters related to deployment of the technologies in an operational setting. EPA emergency responders will use this data to determine if pressurized water decontamination methods can remove IND fallout from urban surfaces.

III. BACKGROUND

Federal Emergency Management Agency (FEMA) is working to prepare for response and recovery to an IND. As a part of these preparations, it is partnering with other government agencies, including the U.S. Environmental Protection Agency (EPA), to perform scientific studies to inform response and recovery. One of these efforts is the assessment of gross decontamination of surfaces contaminated with IND fallout. The EPA was chosen to perform this work because it has the responsibility for clean-up after an IND.

IV. TECHNICAL APPROACH

The Contractor shall adapt existing test methods, protocols, and Quality Assurance Project Plans (QAPP) and shall demonstrate and quantify the performance of rotating jet technology, under realistic conditions, to one urban material (coarse concrete) contaminated with fallout simulant. The Contractor shall evaluate the performance of the rotating jet technology including: the decontamination factor (DF), time required to achieve that decontamination factor, difficulty of using the technology under realistic conditions, and an estimate of the costs (including disposal and secondary wastes estimates), constraints, and other factors such as quantity of waste generated, which would accompany application of the technology in an urban decontamination scenario. The Contractor shall also document other pertinent information relative to the technology application such as equipment required, mobility issues associated with equipment, decontamination of equipment, work crew sizes, and PPE that will affect the technology's effectiveness.

V. TASKS

TASK 1: PREPARATION AND APPROVAL OF THE QAPP PLAN

The awardee shall comply with all requirements as delineated on the "Quality Assurance Planning Requirements Form (QARF)" included with this extramural action, see attachment #1 and #2. The contractor shall prepare a QAPP in accordance with http://www.epa.gov/quality/qs-docs/r5-final.pdf based on the type of research that is being conducted. For guidance on preparing a research-specific QAPP, the preparer should refer to the project specific requirements provided in NHSRC's QMP. The QAPP must be approved by EPA prior to the start of any laboratory work. Additional information related to QA requirements can be found at www.epa.gov/quality.

During development of the QAPP, vendor and stakeholder input shall be solicited and to the extent possible, the QAPP shall be based upon and consistent with the existing QAPP for similar tests. The QAPP shall include a rigorous demonstration of the final test methods and procedures to verify their efficacy. The draft QAPP will be reviewed by the EPA WAM and the EPA Quality Assurance Manager. The contractor shall respond to comments and submit the QAPP for final approval to the EPA WAM and EPA Quality Assurance Manager. The QAPP, including any amendments, must be approved by the USEPA in writing (e.g., signature on the approval page) prior to the start of any work.

TASK 2: GENERATION OF SIMULATED FALLOUT

The contractor shall work with the EPA WAM to establish a suitable simulant for fallout. This simulant shall be tagged with a radionuclide to allow for detection of trace levels of this contaminant. The chemical composition of the fallout shall mimic that seen during surface detonation weapons testing, e.g. sand, and should be tagged with a radionuclide oxide (suitable choices are Sr^{89}, Zr^{95}, or Ca^{45} oxide). The contractor shall also develop a method to reproducibly (± 25%) deposit the contaminant on 6 by 6 inch coarse aggregate concrete coupons in horizontal orientation.

The Contractor shall propose the method to be used to characterize the coupons, both before and after deposition of the contamination (at a minimum the characteristics, distribution, and amount of contamination), and after application of the decontamination technology.

TASK 3: TECHNOLOGY TESTING - EXECUTION

The contractor shall lease the rotating jet technology for this testing and shall obtain coarse aggregate concrete coupons used in previous EPA testing. These coupons shall be nominally 15 cm x 15 cm x 2.5 cm. During testing and deposition, relative humidity shall be maintained and documented at 50% ± 10% RH and ambient temperature shall be maintained and documented at 75 deg F ± 3 deg F. The contractor shall propose the smallest scale testing possible for this technology. Test coupons (5) and positive control coupons (2) shall be contaminated with simulated fallout and subsequently decontaminated using the rotating jet leaving the coupons in

the horizontal orientation. The measured activities from the positive control coupons and the test coupons shall be used to calculate the decontamination factor. In addition to determining the decontamination factor, the Contractor shall evaluate time required to achieve that decontamination factor, difficulty of using the technology under realistic conditions, and an estimate of the costs (including disposal and secondary wastes estimates), constraints, and other factors such as quantity of waste generated, which would accompany application of the technology in an urban decontamination scenario. The Contractor shall also document other pertinent information relative to the technology application such as equipment required, mobility issues associated with equipment, decontamination of equipment, work crew sizes, and PPE that will affect the technology's effectiveness. The Contractor shall operate the equipment/technology being tested according to the procedures (i.e., standard operating procedures, method, instructions, etc.) provided by the vendor and included in the approved QAPP.

TASK 4: DATA SUMMARY

The Contractor shall provide a summary of the data (data brief) plus raw data generated in Tasks 2 and 3.

VI. DELIVERABLE SCHEDULE

1. On a monthly basis for the duration of the project, the contractor shall submit, in electronic format, progress reports summarizing technical progress, problems encountered, monthly and cumulative financial expenditures, and cost and schedule variance.

2. Bi-weekly conference calls shall be established between the EPA WAM and the contractor project officer. During these conference calls the contractor shall report on progress made in the project and any technical issues encountered in implementation of the test plan.

3. Within 30 working days of the issuance of this contract, Quality Assurance Project Plan (QAPP) shall be provided to the EPA, in both electronic format (Microsoft Word, and Adobe), for Task 1-3. The EPA TOPO will then coordinate peer and EPA QA review of the QAPPs. The contractor shall then address any comments resulting from these reviews within 30 days of receipt of the comments. The contractor shall then provide a final copy of the QAPP both in electronic and hard copy for EPA Approval. Work covered in this contract shall not begin until the QAPP has been approved by the EPA Quality Assurance Manager. The QAPPs shall contain work plans detailing how the experiments will be run and include a timetable for task completion. The awardee shall adhere to QA requirements as delineated in "Attachment #1 and 2" to this SOW.

4. Transfer of project data (including raw data) shall occur at the conclusion of the work assignment.

5. A draft data briefing (including data and experimental conditions) shall be submitted within 8 weeks after the completion of the testing in Task 1-4.

VII. REPORTING REQUIREMENTS

1. Data generated as a result of this effort shall be shared with the EPA WAM for internal EPA use.

2. Laboratory data shall be transferred electronically to the EPA WAM after the conclusion of each task.

3. The contractor shall not generate any EPA products but any EPA products (test plans and reports) using the data generated under this work assignment shall be subject to one internal EPA review and one external review.

4. The contractor will not generate any EPA products. Products using the data generated under this SOW shall conform to the requirements of EPA's Handbook for Preparing Office of Research and Development Reports (EPA/800/K-95/002).

Substantive portions of this handbook can be found at www.epa.gov/nhsrc under the policy and guidance tab.

5. Prior to submission of the draft data brief, all of the data shall be given to the EPA WAM in electronic format, specifically Microsoft Excel® spreadsheets. The data contained in these spreadsheets shall be presented and annotated so as to be readily understandable to a wide audience.

6. Copies of any internal audit reports and responses shall be sent to the EPA WAM in a timely fashion. The WAM and EPA Quality Assurance Manager shall be immediately notified of any critical findings.

7. The contractor shall document all data analyses including statistical models and related assumptions.

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 0-5

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-10-001	Base X 10/21/09 - 08/31/10 Option Period Number 2	MARGA Evaluation

Contractor: Batelle

Specify Section and Paragraph of Contract SOW: Section 2.1

Purpose:
- ☐ Work Assignment
- ☐ Work Assignment Amendment
- ☒ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 07/09/10 To 08/31/10

Comments: Work plan approval for MARGA Evaluation

☐ Superfund — Accounting and Appropriations Data — ☐ Non-Superfund

Note: To report additional accounting and appropriations data use EPA Form 1900-69A.

SFO (Max 2): 22

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Contract Period	Cost/Fee	LOE
	10/21/09 - 08/31/10	$ 85,757	494 LOE
This Action:			
Total:			

Work Plan / Cost Estimate Approvals

		Cost/Fee	LOE
Contractor WP Dated:			
Cumulative Approved:			

Work Assignment Manager Name	GARY LEAR	8/4/10	Branch/Mail Code: CAMD/620J Phone Number: 202-343-9159 FAX Number: 202-343-2360
Project Officer Name	SHANNON SERRE	7/23/10	Branch/Mail Code: DCMD/E343-06 Phone Number: 919-541-3817 FAX Number: 919-541-0496
Other Agency Official Name			Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name	LYNNE LEWIS	08/18/10	Branch/Mail Code: NWD Phone Number: 513-487-2040 FAX Number:

(Signature) (Date)

Work Assignment Form. (WebForms v1.0)

Statement of Work

The United States Environmental Protection Agency's (EPA) Office of Atmospheric Programs (OAP) desires to test and evaluate an ambient air monitoring system that will meet the goals and the anticipated needs of the Clean Air Status and Trends Network (CASTNET) as well as other Agency sponsored monitoring programs for the next two to three decades. It is anticipated that these systems will serve other Agency monitoring goals and objectives such as those outlined in the National Air Monitoring Strategy (http://www.epa.gov/ttn/amtic/monitor.html). For more information on CASTNET including program background, atmospheric deposition and concentration data, air quality and deposition maps, CASTNET documentation, and site information visit the CASTNET web site at: http://www.epa.gov/castnet.

I. Introduction

The EPA has initiated a program to investigate advanced measurement systems to meet the emerging needs in air quality and environmental assessments. The EPA is interested in testing and evaluating technically and scientifically advanced measurement methods capable of providing real-time, accurate, and quantitative measurements of ambient gaseous and aerosol constituents. Recent advancements in ambient air measurement instrumentation now provides the capability of remote access to field instruments to monitor operating status and to allow real-time or near real-time (within 24 hours) access to measurement data. The advantages of routine operation of such systems include a much more timely data stream and improved air quality assessment capability. Real-time, multi-pollutant monitoring in rural areas will help the EPA better characterize the extent of regional transport of pollutants (i.e., particulate matter and gaseous precursors), provide improved regional dry deposition estimates, and help in both the development and validation of air quality models. These measurement systems could also be used as an early warning system in the event of an intentional or accidental release of chemicals or agents which may affect human health.

The EPA is interested in testing an advanced monitoring instrument that will meet the rigors of long-term, routine environmental monitoring in remote locations (such as the CASTNET program) and will provide high quality data on a real-time basis. A multi-pollutant monitoring approach will also allow for continued improvement in source apportionment analyses and modeling which is necessary for determining the relative contributions of various emission sources to atmospheric air quality.

In a previous acquisition EPA selected the Monitor for Aerosols and Gases in Ambient Air (MARGA) manufactured by Applikon Analytical for a multi-year development and testing program to determine the feasibility of implementing an advanced, multi-pollutant measurement instrument that provides hourly measurements of both gaseous and aerosol species as part of its routine monitoring network.

II. Project Description

This project is intended to provide an independent evaluation of the MARGA through the Advanced Monitoring Systems (AMS) Center of EPA's Environmental Technology Verification Program (ETV; http://www.epa.gov/etv/basic.html) to determine if the instrument meets the EPA's monitoring requirements and specifications (Attachment A). Instruments from other manufacturers may be evaluated during this project upon request from the instrument vendor and approval by EPA COR. This project shall consist of the preparation of an ETV test/quality assurance (QA) plan, conducting verification testing, providing QA oversight and auditing, and preparing the verification report and a summary statement on the instrument.

The Work Assignment Manager shall provide technical direction for performance of specific tasks under this work assignment. Additional tasks may be issued for the conduct of the testing, data analysis and preparation of reports.

III. Task 1. Preparation of Test/QA Plan

The Contractor shall develop and complete a test/QA plan for verifying compliance of the instruments undergoing testing with the Quality Performance Criteria and Standards in Attachment A. The Contractor shall discuss and coordinate with EPA and laboratory personnel to ensure suitability of the plan for specific conditions at the site and in the laboratory. Under this task the Contractor will prepare and finalize a test/QA plan for performance verification of two collocated units of the MARGA system, specifying procedures to evaluate the MARGA for precision between the two instruments and accuracy relative to EPA reference/equivalent and compendium methods. The Contractor shall recommend any clarifications to the Quality Performance Criteria and Standards in Attachment A to ensure accurate, reliable, and consistent results of the testing. The test/QA plan will be prepared in the standard ETV AMS Center format. The Contractor will coordinate with Dr. John Walker (EPA/ORD), Mr. Mark Hodges (MACTEC Engineering and Consulting), and other groups performing sampling at the site in developing the plan. The Contractor shall prepare a draft of the test/QA plan and submit it for approval by the ETV AMS Center. Upon approval, the final test/QA plan will be distributed to all parties involved in the verification testing.

IV. Task 2. Verification Testing

The Contractor shall conduct the verification testing of instruments in accordance with the Test/QA Plan developed in Task 1. The verification testing shall be jointly coordinated and conducted by the EPA and the Contractor at the EPA facility in Research Triangle Park (RTP), NC. Two MARGA instruments will be set up in a field trailer and operated by EPA personnel. EPA personnel will obtain and deliver instrument-validated data from the MARGA to the Contractor within 24 hours of data retrieval, and such data delivery will be performed daily during normal work days throughout the testing period.

The Contractor shall provide an on-site Test Coordinator to oversee the testing efforts, observe the operation of the test instruments, operate reference instruments and samplers,

and ensure that all needed samples, analyses and data records are obtained. In addition, the Contractor will perform QA oversight and auditing of the test procedures. That QA activity will include one trip to conduct both a one-day on-site Technical Systems Audit at the RTP test site and a comparable one-day TSA at the MACTEC reference analytical lab. An Audit of Data Quality will also be conducted on at least 10% of the test data during the reporting process.

Reference method samples shall be collected every twelve hours throughout the testing period from duplicate collocated measurement systems. The reference method measurement systems shall be located near or on top of the trailer. Reference sampling shall begin a minimum of 7 days before the beginning of the testing period to demonstrate reference tests are in control and providing reliable and accurate data. The Contractor shall ship reference samples for overnight delivery to the analytical laboratory within 24 hours of collection. EPA will provide for preparation and analysis of reference samples according to the procedures specified in the testing protocol. Results from laboratory analyses obtained in the first 7 days of sampling, or until reference sampling is demonstrated to be in control, will be provided to all participants within 5 days of receipt of samples by the laboratory. Results from laboratory analyses obtained during the remainder of the test period will be provided to all participants within 15 days of receipt of samples.

Verification testing shall be conducted for 30 consecutive days in August 2010, or as soon thereafter as possible.

V. Task 3. Data Analyses and Report

The Contractor shall evaluate the performance of the MARGA systems by the criteria and methods set forth in the Test/QA Plan. The Contractor shall prepare a draft ETV verification report on the verification results in the standard ETV AMS Center format, and submit the report for approval by the ETV AMS Center. The report shall be revised and finalized based on review comments.

VI. Deliverables:

(1) Work Plan	Within 15 days from issuance of work assignment
(2) Draft Test/QA Plan	Within 15 days from issuance of work assignment
(3) Final Test /QA Plan	Within 30 days from issuance of work assignment
(4) Draft Report	Within 60 days of completion of testing period
(5) Final Report	Within 30 days of receipt of comments

Attachment A. Quality Performance Criteria and Standards

Performance Goal	Measurement	Method	Standard
Accuracy Goal 1	SO2, HNO3, NH3, SO42_, NO3_, and NH4+	Slope (m) of linear regression by least-squares method of mean value of reference measurements paired with measurement of each instrument. All data with mean reference values below 2 times the instrument detection limit (IDL) are excluded.	$0.80 \leq m \leq 1.20$
Accuracy Goal 2	SO2, HNO3, NH3, SO42_, NO3_, and NH4+	Intercept (b) of linear regression by least_squares method of mean value of reference measurements paired with measurement of each instrument. All data with mean reference values below 2 times the IDL are excluded.	10 ppb $\leq b \leq$ 10 ppb
Accuracy Goal 3	SO2, HNO3, NH3, SO42_, NO3_, and NH4+	The median absolute relative percent differences (MARPD) between the mean value of reference measurements paired with measurement of each instrument.	MARPD $\leq$ 40%
Accuracy Goal 4 (If the instrument does not meet Accuracy Goal 3)	SO2, HNO3, NH3, SO42_, NO3_, and NH4+	Perform Wilcoxon matched pairs test to determine if the failure to achieve Accuracy Goal 3 is due to expected measurement variation. The ratio of observed differences in the two data sets (i.e., reference and instrument) to expected random differences in the same two data sets.	p_value $\leq$ 0.05
Precision Goal 1	SO2, HNO3, NH3, SO42_, NO3_, and NH4+	Median absolute relative percent difference (MARPD) between paired instrument measurements. All data with mean instrument values below 2 times the IDL are excluded.	MARPD $\leq$ 25%
Precision Goal 2	SO2, HNO3, NH3, SO42_, NO3_, and NH4+	Median absolute relative percent difference between paired instrument measurements (RPD0.5) is less than the 95th percentile of the pooled RPD of the reference method (RPD REF0.95).	$RPD_{0.5} \leq RPD_{REF0.95}$
Completeness Goal 1	SO2, HNO3, NH3, SO42_, NO3_, and NH4+, Na+, Ca+, Cl_	Percentage of test period for which valid data, as indicated by the instrument, is available within 24 hours of collection.	$T_{valid} \geq 80\%$
Completeness Goal 2	SO2, HNO3, NH3, SO42_, NO3_, and NH4+, Na+, Ca+, Cl_	Completeness of data record for comparison with reference measurements for each test period, when detected by reference measurements (i.e., hours of valid measurements for each valid reference measurement period).	$T_{Reference} \geq 80\%$
Reliability Goal 1	Instrument measurement mode	Percentage of time instrument is in measurement mode for test period	$T_{Measurement} \geq 90\%$

Reliability Goal 2	Power failure tolerance	In the event of a power failure the instrument has sufficient back_up power to perform a controlled shutdown, restarts, and instrument returns to measurement mode within 4 hours after power has returned.	Yes/No
Reliability Goal 3	Operator attendance	Average number of site visits per week required to keep instrument operating.	$N \leq 2$

United States Environmental Protection Agency
Washington, DC 20460

EPA Work Assignment

Work Assignment Number: 0-6

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-10-001	Base: Option Period Number 2:	Revision of Report on Systematic

Contractor	Specify Section and Paragraph of Contract SOW
Batelle	Section 3.1

Purpose:
☐ Work Assignment
☐ Work Assignment Amendment
☒ Work Plan Approval
☐ Work Assignment Close-Out
☐ Incremental Funding

Period of Performance: From 7/9/10 To 08/31/10

Comments: Work plan approval for Revision Of Report On Systematic Investigation Of Liquid And Fumigant Decontamination Efficacy Against Biological Agents Deposited On Test Coupons Of Common Indoor Materials.

☐ Superfund — Accounting and Appropriations Data — ☐ Non-Superfund

Note: To report additional accounting and appropriations data use EPA Form 1900-69A.

SFO (Max 2): 22

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: Base Period	$16,350	105 LOE
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: SHAWN RYAN (Signature)	(Date): 8/6/10	Branch/Mail Code: DCMD/E343-06 Phone Number: 919-541-0699 FAX Number: 919-541-0496
Project Officer Name: SHANNON SERRE (Signature)	(Date): 7/23/10	Branch/Mail Code: DCMD/E343-06 Phone Number: 919-541-3817 FAX Number: 919-541-0496
Other Agency Official Name (Signature)	(Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: LYNNE LEWIS (Signature)	(Date): 8/20/10	Branch/Mail Code: NWD Phone Number: 513-487-2040 FAX Number:

Work Assignment Form. (WebForms v1.0)

STATEMENT OF WORK
Contract EP-C-10-001

I. TITLE
Revision of Report on Systematic Investigation of Liquid and Fumigant Decontamination Efficacy against Biological Agents Deposited on Test Coupons of Common Indoor Materials

II. PERIOD OF PERFORMANCE
The period of performance for the tasks detailed in this Statement of Work (SOW) shall be until August 31, 2010.

III. SUMMARY OF OBJECTIVES
This work will provide a revision of the report on "Systematic Investigation of Liquid and Fumigant Decontamination Efficacy against Biological Agents Deposited on Test Coupons of Common Indoor Materials" completed under a previous contract agreement with Battelle.

IV. RELEVANCE
The report will provide the decontamination technology user and stakeholder with high quality, peer-reviewed data on the effectiveness of liquids and fumigants to decontaminate building materials contaminated with *B. anthracis,* ricin toxin, and vaccinia virus.

V. BACKGROUND
The U.S. Environmental Protection Agency (EPA) has the responsibility for protecting human health and the environment from accidental and intentional releases of hazardous and toxic materials. According to Homeland Security Presidential Directive 10 (HSPD-10), the EPA is tasked with developing strategies, guidelines, and plans for decontamination of persons, equipment, and facilities following a biological weapons attack. In response to this directive, the EPA Office of Research and Development (ORD) National Homeland Security Research Center's (NHSRC) Decontamination and Consequence Management Division (DCMD) is investigating methods and technologies for the inactivation of spores (e.g., *Bacillus anthracis* Ames) on materials/surfaces. This work will build on the decontamination studies that have already been conducted.

VI. SCOPE

The purpose of the effort is to revise the report based upon comments received during quality assurance and peer review of the document received as the deliverable under a prior vehicle with Battelle. While the deliverable was acceptable, addressing such comments is required by EPA for future use of the report.

VII. TECHNICAL APPROACH

Comments will be provided to the contractor by the EPA work assignment manager (WAM). This shall include a set of comments from the EPA quality assurance manager, 3 sets from the peer reviewers, and one from the EPA WAM. The contractor shall revise the report per the comments and provide documentation of changes made to the report and response to comments.

VIII. TASKS

There is only one task for this effort. The contractor shall revise the report per the comments. The revised report shall be one deliverable for this effort. Additionally, the contractor shall prepare documentation of the changes made and responses to all comments. It is anticipated that calls with the EPA WAM will be required to discuss the disposition of comments.

IX. QUALITY ASSURANCE

The awardee shall comply with all requirements as delineated on the "Quality Assurance Planning Requirements Form (QARF)" included with this extramural action; see attachment #1 and #2.

X. DELIVERABLE SCHEDULE

The final report and document of disposition of comments shall be delivered by August 31, 2010. The report developed under this SOW (e.g., the above mentioned technical report) shall conform to the requirements of EPA's Handbook for Preparing Office of Research and Development Reports (EPA/800/K-95/002). Substantive portions of this handbook can be found at www.epa.gov/nhsrc under the policy and guidance tab.

NHSRC QUALITY ASSURANCE REQUIREMENTS FORM
Attachment 1 to the Statement of Work

I GENERAL INFORMATION

Title:	Revision of Report on Systematic Investigation of Liquid and Fumigant Decontamination Efficacy against Biological Agents Deposited on Test Coupons of Common Indoor Materials
Description:	This work will provide a revision of the report on "Systematic Investigation of Liquid and Fumigant Decontamination Efficacy against Biological Agents Deposited on Test Coupons of Common Indoor Materials" completed under a previous contract agreement with Battelle.
Project ID:	DCMD 3.10A
Status:	Original
Number Ammended:	
QA Category:	III
Action Type:	Extramural
Peer Review Category:	IV
Security Classification:	Unclassified
Project Type:	Applied Research
QAPP Status 1:	Endorsed
QAPP Status 2:	Not Applicable
QAPP Status 3:	Not Applicable
Vehicle Status:	Existing Vehicle
Vehicle Type:	Vehicle Number: FP-C-10-001 Ac k Assignment Number: TBD Delivery/Task Order Number: na Modification Number: 0 Other: na

*If you are processing an **IAG** or **CRADA**, the responsibility for QA must be negotiated within the agreement. The TLPs in consultation with the QAMs in the various organizations must agree on, and document, which organization will take the lead for QA, the names of the QAM and TLP from each organization, and the QA requirements that will be adhered to during the agreement. Include this info in the IAG/CRADA package.*

II SCOPE OF WORK

Yes — Does the Statement of Work contain the appropriate QA language?

The awardee shall comply with all requirements as delineated on the "Quality Assurance Planning Requirements Form (QARF)" included with this extramural action. The contractor shall prepare a QAPP in accordance with the R-2 and R-5 and/or the attachments provided with the SOW. The QAPP must be approved prior to the start of any work. Additional information related to QA requirements can be found at http://www.epa.gov/quality/qs-docs/r5-final.pdf

Yes — Does this extramural action involve the collection, generation, use, and/or reporting of environmental data; the design, construction, and operation of environmental technologies; or development of software, models, or methods?
(If "No" then skip to Section IV, and sign the form.)

No — Will the SOW or any subsequent work assignments or task orders involve any cross-organizational efforts within EPA?

Yes Has a QAPP already been approved for the activities specified in the SOW?

Provide the title, date or revision number, and date of QA approval:

Battelle, Test/QA Plan for Systematic Evaluation of the Chlorine Dioxide Technology for Decontamination of Biological Agents from Contaminated Indoor Surfaces Version 1. January 2006.
Battelle, Test/QA Plan for Systematic Fumigation Chamber Investigation of Methyl Bromide Efficacy Against Biological Agents Deposited on Test Coupons Derived from Common Indoor Materials. June 2007.
Battelle, Test/QA Plan for Systematic Investigation of Liquid Technologies for Decontamination of Biological Agents from Contaminated Indoor Surfaces. September 2006.

Does the QAPP require any revision by the contractor**

NO

No Is an applicable QAPP in the process of being prepared, revised, or approved by EPA personnel for future use by the contractor? (QA approval must be obtained before the contractor can start work.)

** *The term "contractor" applies loosely here, such that as applicable, this term can also mean "awardee", "cooperator" and/or "grantee". Likewise, the term "contract" includes "agreements" and other vehicles.*

III QA DOCUMENTATION OPTIONS

All documentation specified under "Other" must be defined in the NHSRC Quality Management Plan and be consistent with requirements defined in EPA Manual 5360 A1. For all items checked below, there must be adequate information in the SOW (or its appendices) for the offeror to develop this documentation. Where applicable, reference a specific section of the SOW. *(R-2 refers to EPA Requirements for Quality Management Plans (QA/R-2) (EPA/240/B-01/002, 03/20/01) and R-5 refers to EPA Requirements for Quality Assurance Project Plans (QA/R-5) (EPA/240/B-01/003, 03/20/01). Copies of these documents are available at http://www.epa.gov/quality/qa_docs.html.)*

After Award Documentation

Not Applicable	Documentation of an organization's Quality System. QMP developed in accordance with:
Not Applicable	Combined documentation of an organization's Quality System and application of QA and QC to the single project covered by the contract: Developed in accordance with:
Not Applicable	Documentation of the application of QA and QC activities to applicable project(s). Developed in accordance with:
na	Programmatic QA Project Plan with supplements for each specific project, developed in accordance with:
Not Applicable	Existing documentation of the application of QA and QC activities will be used:

IV SIGNATURE BLOCK

The signatures below verify that the Statement of Work (SOW) has been reviewed to ascertain the necessary QA and QC activities required to comply with EPA Order 5360.1 A2, that the COR understands these requirements, and that the COR will ensure that the quality requirements indicated on the previous pages of this form are incorporated into all associated SOWs. *(Sign/date below, obtain a concurrence signature from the QA Staff, and submit the form along with the other extramural action documentation.)*

Shawn Ryan NHSRC-DCMD Technical Lead Person	06/24/2010 Date	Fletha Roberts NHSRC-IO QA Staff Member	06/24/2010 Date

QAPP REQUIREMENTS FOR APPLIED RESEARCH PROJECTS
(from Appendix B of the NHSRC QMP)

An applied research project is a study to demonstrate the performance of technologies under defined conditions. These studies are often pilot- or field-scale. The following requirements should be addressed as applicable.

SECTION 0.0, APPROVAL BY PROJECT PARTICIPANTS

The EPA Technical Lead Person (TLP) shall be responsible for obtaining signatures of appropriate project participants on the signature page of the QA plan, documenting agreement to project objectives and the approach for evaluating these objectives.

A distribution list shall be provided to facilitate the distribution of the most recent current version of the QAPP to all the principal project participants.

SECTION 1.0, PROJECT DESCRIPTION AND OBJECTIVES

1.1 The purpose of study shall be clearly stated.

1.2 The process, site, facility, and/or environmental system to be tested shall be described.

1.3 Project objectives shall be clearly stated and identified as primary or non-primary.

SECTION 2.0, PROJECT ORGANIZATION

2.1 Key points of contact for each organization involved in the project shall be identified.

2.2 All QA Managers and their relationship in the organizations (*i.e.*, location within each organization) shall be identified with evidence that the QA Manager is independent of project management.

2.3 Responsibilities of all other project participants and their relationship to other project participants shall be identified, meaning that organizations responsible for planning, coordination, sample collection, sample custody, measurements (*i.e.*, analytical, physical, and process), data reduction, data validation, and report preparation shall be clearly identified.

SECTION 3.0, EXPERIMENTAL APPROACH

3.1 The general approach and the test conditions for each experimental phase shall be provided. The statistical methods that will be used to evaluate the data (*i.e.*, ANOVA, or summary statistics) should be identified.

(NOTE: As deemed appropriate to the project by the TLP, the information requested in Sections 3.2, 3.3, and 3.4 may be presented here or in Section 4; the information requested in Sections 3.5 may be presented here or in Section 5; and the information requested in Sections 3.6 may be presented here or in Section 7.)

3.2 The sampling strategy shall be included and evidence must be presented to demonstrate that the strategy is appropriate for meeting primary project objectives, *i.e.*, a description of the statistical method or scientific rationale used to select sample sites and number of samples shall be provided.

3.3 Sampling/monitoring points for all measurements (*i.e.*, including locations and access points) shall be identified.

3.4 The frequency of sampling/monitoring events, as well as the numbers for each sample type and/or location shall be provided, including QC and reserve samples.

3.6 All measurements (*i.e.*, analytical [chemical, microbiological, assays], physical, and process) shall be identified for each sample type or process, and project-specific target analytes shall be listed and classified as critical or noncritical in the QAPP.

3.6 The planned approach (statistical and/or non-statistical) for evaluating project objectives shall be included.

SECTION 4.0, SAMPLING PROCEDURES

4.1 Whenever applicable, the method used to establish steady-state conditions shall be described.

4.2 Known site_specific factors that may affect sampling/monitoring procedures shall be described.

4.3 Any site preparation needed prior to sampling/monitoring shall be described.

4.4 Each sampling/monitoring procedure to be used shall be discussed or referenced. If compositing or splitting samples, those procedures shall be described.

4.5 For samples requiring a split sample for either QA/QC purposes or for shipment to a different laboratory, the QAPP shall identify who is responsible for splitting samples, and where the splitting is performed (*e.g.*, field versus lab)

4.6 If sampling/monitoring equipment is used to collect critical measurement data (*i.e.*, used to calculate the final concentration of a critical parameter), the QAPP shall describe how the sampling equipment is calibrated, the frequency at which it is calibrated, and the acceptance criteria for calibration or calibration verification, as appropriate.

4.7 If sampling/monitoring equipment is used to collect critical measurement data, the QAPP shall describe how cross-contamination between samples is avoided.

4.8 The QAPP shall include a discussion of the procedures to be used to assure that representative samples are collected.

4.9 A list of sample quantities to be collected, and the sample amount required for each analysis, including QC sample analysis, shall be specified.

4.10 Containers used for sample collection, transport, and storage for each sample type shall be described.

4.11 Describe how samples are uniquely identified.

4.12 Sample preservation methods (*e.g.*, refrigeration, acidification, *etc.*), including specific reagents, equipment, and supplies required for sample preservation shall be described.

4.13 Holding time requirements shall be noted.

4.14 Procedures for packing and shipping samples shall be described.

4.15 Procedures to maintain chain_of_custody (*e.g.*, custody seals, records) during transfer from the field to the laboratory, in the laboratory, and among contractors and subcontractors shall be described to ensure that sample integrity is maintained.

4.16 Sample archival requirements for each relevant organization shall be provided.

SECTION 5.0, TESTING AND MEASUREMENT PROTOCOLS

5.1 Each measurement method to be used shall be described in detail or referenced. Modifications to EPA_approved or similarly validated methods shall be specified.

5.2 For unproven methods, verification data applicable to expected matrices shall be included in the QAPP meaning the QAPP shall provide evidence that the proposed method is capable of achieving the desired performance.

5.3 For measurements which require a calibrated system, the QAPP shall include specific calibration procedures applicable to each project target analyte, and the procedures for verifying both initial and continuing calibrations (including frequency and acceptance criteria, and corrective actions to be performed if acceptance criteria are not met).

SECTION 6.0, QA/QC CHECKS

6.1 At a minimum, the QAPP shall include quantitative acceptance criteria for QA objectives associated with accuracy, precision, detection limits, and completeness for critical measurements (process, physical, and analytical, as applicable) for each matrix.

6.2 Any additional project-specific QA objectives shall be presented, including acceptance criteria. This includes items such as mass balance requirements.

6.3 The specific procedures used to assess all identified QA objectives shall be fully described.

6.4 The QAPP shall list and define all other QC checks and/or procedures (*e.g.*, blanks, surrogates, controls, *etc.*) used for the project, both field and laboratory.

6.5 For each specified QC check or procedure, required frequencies, associated acceptance criteria, and corrective actions to be performed if acceptance criteria are not met shall be included.

SECTION 7.0, DATA REPORTING, DATA REDUCTION, AND DATA VALIDATION

7.1 The reporting requirements (*e.g.*, units, reporting method [wet or dry]) for each measurement and matrix shall be identified.

7.2 The deliverables expected from each organization responsible for field and laboratory activities shall be listed.

7.3 Data reduction procedures specific to the project, and also specific to each organization, shall be summarized.

7.4 Data validation procedures specific to each organization used to ensure the reporting of accurate project data to internal and external clients shall be summarized.

7.5 Data storage requirements for each organization shall be provided.

7.6 The product document that will be prepared for the project shall be specified (*e.g.*, journal article, final report, *etc.*). The contents of this document can be referenced to a NHSRC or program-specific QMP, if appropriate.

SECTION 8.0, ASSESSMENTS

8.1 The QAPP shall identify all scheduled audits (*i.e.*, both technical system audits [TSAs] and performance evaluations [PEs]) to be performed, who will perform these audits, and who will receive the audit reports.

8.2 The QAPP shall provide procedures that are to be followed that will ensure that necessary corrective actions will be performed.

8.3 The responsible party(-ies) for implementing corrective actions shall be identified.

SECTION 9.0, REFERENCES

References shall be provided either in the body of the text as footnotes or in a separate section.

Attachment # 2

NHSRC QA
To the Statement of Work
Requirements/Definitions List

EPAs Quality System Website: http://www.epa.gov/quality
EPA's Requirements and Guidance Documents: http://www.epa.gov/quality/qa_docs.html
EPA's Quality System Website: http://www.epa.gov/quality/qs-docs/r5-final.pdf

In accordance with EPA Order 5360.1 A2, conformance to ANSI/ASQC E4 must be demonstrated by submitting the quality documentation described herein. All Quality documentation shall be submitted to the Government for review. The Government will review and return the quality documentation, with comments, and indicate approval or disapproval. If the quality documentation is not approved, it must be revised to address all comments and shall be resubmitted to the Government for approval. Work involving environmental data collection, generation, use, or reporting shall not commence until the Government has approve the quality documentation. The Quality Assurance Project Plan (QAPP) shall be submitted to the Government at least thirty (30) days prior to the beginning of any environmental data gathering or generation activity in order to allow sufficient time for review and revisions to be completed. After the Government has approved the quality documentation, the Contractor shall also implement it as written and approved by the Government.

NHSRC's Quality System Specifications for Extramural Actions –

These requirements typically pertain to single project efforts. The five specifications are:

(1) **a description of the organization's Quality System (QS) and information regarding how this QS is documented, communicated and implemented;**
(2) **an organizational chart showing the position of the QA function;**
(3) **delineation of the authority and responsibilities of the QA function;**
(4) **the background and experience of the QA personnel who will be assigned to the project; and**
(5) **the organization's general approach for accomplishing the QA specifications in the SOW.**

NHSRC QA Requirements/Definitions List
Category Level Designations (determines the level of QA required):

☐ **Category I Project** - applicable to studies performed to generate data used for enforcement activities, litigation, or research project involving human subjects. The QAPP shall address all elements listed in "EPA Requirements for QA Project Plans, EPA QA/R-5.

☐ **Category II Project** - applicable to studies performed to generate data used in support of the development of environmental regulations or standards. The QAPP shall address all elements listed in "EPA Requirements for QA Project Plans, EPA QA/R-5.

☒ **Category III Project** - applicable to projects involving applied research or technology evaluations. The QAPP shall address the applicable sections of "EPA Requirements for QA Project Plans, EPA QA/R-5 as outlined in the **NHSRC's QMP: QAPP** requirements for the specific project type (see below).

☐ **Category IV Project** - applicable to projects involving basic research or preliminary data gathering activities. The QAPP shall address the applicable sections of "EPA Requirements for QA Project Plans, EPA QA/R-5 as outlined in the **NHSRC's QMP QAPP** requirements for the specific project type (see below).

Project Types:

These outlines of NHSRC's QAPP Requirements for various project types from Appendix B of the NHSRC QMP (except where otherwise noted), are condensed from typically applicable sections of R-5 (EPA Requirements for QA Project Plans) and are intended to serve as a starting point when preparing a QAPP. These lists and their format may not fit every research scenario and QAPP's must conform to applicable sections of R-5 in a way that fully describes the research plan and appropriate QA and QC measures to ensure that the data are of adequate quality and quantity to fit their intended purpose.

☒ **Applied Research Project** - pertains to a study performed to generate data to demonstrate the performance of accepted processes or technologies under defined conditions. These studies are often pilot- or field-scale. The QAPP shall address all requirements listed in "QAPP Requirements for Applied Research Projects" from Appendix B of the NHSRC QMP.

☐ **Basic Research Project** - pertains to a study performed to generate data used to evaluate unproven theories, processes, or technologies. These studies are often bench-scale. The QAPP shall address all requirements listed in "QAPP Requirements for Basic Research Projects" from Appendix B of the NHSRC QMP.

☐ **Design, Construction, and/or Operation of Environmental Technology Project** - pertains to environmental technology designed, constructed and/or operated by and/or for EPA. The QAPP shall address requirements in the EPA Quality System document "Guidance on Quality Assurance for Environmental Technology Design, Construction, and Operation" G-11, at http://www.epa.gov/quality/QS-docs/g11-final-05.pdf. For additional information, you may refer to Part C of "Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology," ANSI/ASQC E4-1994, American Society for Quality Control, Milwaukee, WI, January 1995.

☐ **Geospatial Data Quality Assurance Project** - pertains to data collection; data processing and analysis; and data validation of geospatial applications. The QAPP shall address requirements in the EPA Quality System document "Guidance for Geospatial Data Quality Assurance Project Plans" G-5S at http://www.epa.gov/quality/QS-docs/g5g-final-05.pdf.

☐ **Method Development Project** - pertains to situations where there is no existing standard method, or a standard method needs to be significantly modified for a specific application. The QAPP shall address all requirements listed in "QAPP Requirements for Method Development Projects" from Appendix B of the NHSRC QMP.

☐ **Model Development Project** - includes all types of mathematical models including static, dynamic, deterministic, stochastic, mechanistic, empirical, etc. The QAPP shall address requirements in the EPA Quality System document "Guidance for Quality Assurance Project Plans for Modeling" G-5M at http://www.epa.gov/quality/QS-docs/g5m-final.pdf.

☐ **Sampling and Analysis Project** - pertains to the collection and analysis of samples with no objectives other than to provide characterization or monitoring information. The QAPP shall address all requirements listed in "QAPP Requirements for Sampling and Analysis Projects" from Appendix B of the NHSRC QMP.

☐ **Secondary Data Project** - pertains to environmental data collected from other sources, by or for EPA, that are used for purposes other than those originally intended. Sources may include: literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. The QAPP shall address all requirements listed in "QAPP Requirements for Secondary Data Projects" from Appendix B of the NHSRC QMP.

☐ **Software Development and Data Management Project** - pertains to software development, software/hardware systems development, database design and maintenance, data validation and verification systems. The QAPP shall address all requirements listed in "QAPP Requirements for Software Development Projects" from Appendix B of the NHSRC QMP.

Definitions:

Environmental Data - These are any measurement or information that describe environmental processes, location, or conditions; ecological or health effects directly from measurements, produced from software and models, and compiled from other sources such as data bases or the literature. For EPA, environmental data include information collected directly from measurements, produced from software and models, and compiled from other sources such as data bases or literature.

Incremental Funding - Incremental funding is partial funding, no new work.

Quality Assurance (QA) - Quality assurance is a system of management activities to ensure that a process, item, or service is of the type and quality needed by the customer. It deals with setting policy and running an administrative system of management controls that cover planning, implementation, and review of data collection activities and the use of data in decision making. Quality assurance is just one part of a quality system.

Quality Assurance Project Plan (QAPP) - A QAPP is a document that describes the necessary quality assurance, quality control, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria. A QAPP documents project-specific information.

Quality Control (QC) - Quality control is a technical function that includes all the scientific precautions, such as calibrations and duplications, which are needed to acquire data of known and adequate quality.

Quality Management Plan (QMP) - A QMP is a document that describes an organization's/program's quality system in terms of the organizational structure, policy and procedures, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, documenting, and assessing all activities conducted. A QMP documents the overall organization/program, and is primarily applicable to multi-year, multi-project efforts. An organization's/program's QMP shall address all elements listed in the "Requirements for Quality Management Plans" in Appendix B of the NHSRC QMP.

Quality System - A quality system is the means by which an organization manages its quality aspects in a systematic, organized manner and provides a framework for planning, implementing, and assessing work performed by an organization and for carrying out required quality assurance and quality control activities.

R-2. EPA Requirements for Quality Management Plans (EPA/240/B-01/002) March, 2001 http://www.epa.gov/quality/QS-docs/r2-final.pdf.

R-5. EPA Requirements for Quality Management Plans (EPA/240/B-01/002) March, 2001 http://www.epa.gov/quality/QS-docs/r5-final.pdf.

Substantive Change - Substantive change is any change in an activity that may alter the quality of data being used, generated, or gathered.

Technical Lead Person (TLP) - This person is technically responsible for the project. For extramural contract work, the TLP is typically the contracting officer's representative (COR). For intramural work, the TLP is typically the Principal Investigator.

Abbreviations:

COR	Contracting Officer's Representative	IAG	Interagency Agreement
NHSRC	National Homeland Security Research Center	QA	Quality Assurance
NRMRL	National Risk Management Research Laboratory	QAM	Quality Assurance Manager
QA ID	Quality Assurance Identification	QMP	Quality Management Plan
QAPP	Quality Assurance Project Plan	SOW	Statement of Work
QS	Quality System	CRADA	Cooperative Research & Development Agreement
TLP	Technical Lead Person		